American Academy of Orthopaedic Surgeons® | AAOS American Association of Orthopaedic Surgeons

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Jane E. Henney, MD
Commissioner
Food and Drug Administration (FDA)
Rockville, Maryland 20852

Dear Dr. Henney:

The American Academy of Orthopaedic Surgeons (AAOS), representing over 16,000 Board certified orthopaedic surgeons, welcomes this opportunity to comment on the FDA's Guidance Document: Reprocessing and Reuse of Single-Use Devices (SUDs); Review of Prioritization Scheme. (Published in the Federal Register on Friday, February 11, 2000. [Docket No. 00D-0053]).

The AAOS recognizes the importance of the FDA's efforts to provide guidance to ensure and enhance patient safety in the complex area of reprocessing and reusing SUDs. However, we are concerned about the possible unintended consequences of the guidance document on the physician community. This document raises a number of issues that the AAOS believes must be addressed by the FDA. Our comments will focus on the following areas of concern:

- FDA's visual inspection approach for determining "inadequate performance risk" is unacceptable and inappropriate;
- While the prioritization scheme may be a good one, the most important factor is that all high risk SUDs must be clearly identified;
- All orthopaedic SUDs should be in the low risk category;
- The development of standards and other research initiatives are of critical importance to the regulation of SUDs; and,
- An appropriate mechanism should be in place to enforce and review the FDA SUD classification.

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FDA's visual inspection approach for determining inadequate performance risk is unacceptable and inappropriate

The AAOS has serious concerns about the visual inspection requirement to determine whether a device is classified as moderate or low risk. Regardless of whether a device is new or reprocessed and whether it is clearly labeled as new or reprocessed, we contend that visual inspection with the naked eye is insufficient to reveal damage, degradation, or latent defects that may have occurred in the manufacturing or reprocessing of a device. Moreover, upon visual inspection, many SUDs used in orthopaedic surgery, including drill bits and saw blades, may appear to be functional but may not, after reprocessing, maintain the same characteristics as new instruments. A dull drill bit or saw blade usually cannot be identified as such visually, but is quickly and routinely replaced by a new one when necessary during surgery. This poses no risk to the patient. Therefore, the visual inspection criterion in the algorithm is flawed, and inappropriately assigns SUDs to a high risk category.

It is the belief of the AAOS that these types of orthopaedic devices, regardless of whether they are new or reprocessed, present low risk to the patient. Thus, the visual inspection criterion for these orthopaedic devices adds nothing to protect the patient from risk. However, by adding this visual inspection requirement, the FDA will have inadvertently shifted the burden (and standard of care) to the physician, with regard to injury caused to a patient due the failure of a SUD.

Traditionally, under product liability law, it is the manufacturer (and/or reprocessor) who is generally considered "strictly liable" for injury when it is shown that a product is defective. The FDA's visual inspection criterion may be interpreted to place the burden on the practitioner to inspect and identify defects. This visual inspection component is a deviation from well established product liability law that holds the manufacturer liable for defects and, as mentioned above, has the unintended consequences of shifting the burden and standard of care to the physician.

Any regulatory approach that places the physician at additional risk (or shifts the liability or standard of care to the physician) would not be acceptable. Therefore, we strongly urge the FDA to remove visual inspection from any "decision-tree" to determine classification of a device into a risk category. Other criteria should be used to make this determination.

While the prioritization scheme may be a good one, the most important factor is that all high risk SUDs must be clearly identified

The AAOS concurs that patient safety is best served when SUDs are categorized based on the risk of infection transmission and the risk of inadequate performance, and we agree with the creation of risk categories.

The AAOS has carefully reviewed the list of "Frequently Reprocessed SUDs" included in the February 8, 2000 guidance document, and believes that the FDA must make every effort to ensure that all SUDs currently in use are listed in the compendium in Appendix 2. We particularly want to emphasize that the FDA must clearly and explicitly identify all devices that it considers to be in the high risk category. These high risk SUDs should be the focus of FDA regulation and intervention. Moreover, the AAOS strongly suggests that all devices that are not listed in Appendix 2 or subsequent revisions should be considered to be devices that overall present a low risk when reprocessed.

All reprocessed orthopaedic devices should be in the low risk category

The AAOS maintains that all orthopaedic devices that are now being reprocessed should be in the low risk category.

Carpal tunnel blades - -We would disagree with the categorization of carpal tunnel blades in the moderate risk category, thus subjecting these devices to increased scrutiny and regulatory requirements. It is our experience that carpal tunnel blades are similar in design to many arthroscopy instruments, which the FDA has rated as low risk devices. The AAOS believes that carpal tunnel blades should be categorized as a low risk device and should remain a Class I device, exempt from pre-market submissions.

Bone biopsy needles - -We have noted that biopsy needles (in the general surgery category) are listed as a high risk device. Biopsy needles used in orthopaedic surgery tend to have a larger gauge than those used in general surgery. Therefore, the AAOS suggests that due to the large gauge of this needle, this device should be placed in the low risk category.

The AAOS would like to take this opportunity to commend the FDA for recognizing that endoscopes and arthroscopes are reusable, and that they can be reprocessed safely (well - accepted methods of sterilization exist). We are pleased that subsequent to the release of this guidance document, these devices were removed from the SUDs listing in Appendix 2.

The development of standards and other research initiatives are of critical importance to the regulation of SUDs

Since the passage of the Food and Drug Administration Modernization Act (FDAMA) in 1997, the FDA, especially the Center for Devices and Radiological Health, has placed a greater reliance on the use of consensus standards. The AAOS maintains the strong belief that the use of consensus standards is appropriate to reasonably ensure the safety and efficacy of medical devices, and to guide the review and approval of devices in an expeditious manner. The AAOS is very committed to the process of developing medical and surgical standards that will assist in ensuring patient safety. We encourage the development of standards that provide guidance on the reprocessing of single use devices as well as provide the minimum acceptable levels of sterility and performance.

However, if the FDA guidance document results in the over-regulation of low risk devices, we are very concerned and troubled that the FDA may force appropriate entities to develop standards and engage in activities to demonstrate safety and efficacy when no real patient risk is present.

The AAOS is unaware of any study or data that suggest that malfunctions or defects of reusable or reprocessed devices used by orthopaedic surgeons have led to an adverse outcome or injury to a patient. Further study is necessary in order to identify whether a problem exists and what the scope of the problem might be with regard to single use device reprocessing. The AAOS supports the FDA's intentions to implement a research program to explore safety and effectiveness issues associated with the reprocessing of single use devices.

The AAOS also encourages the collection of post-market data, including but not limited to laboratory reports and published data, to determine if reprocessed single use devices present an increased risk of infection or are subject to inadequate performance.

In addition, as the FDA moves forward on this issue, the AAOS encourages the FDA to develop a reporting process that ensures confidentiality. As the FDA has noted in the past, Medical Device Reports (MDRs) do not facilitate accurate assessment of device failure rates, nor do they allow the proper tracking of infections that may have resulted from an improperly reprocessed SUD. The AAOS strongly supports federal legislative initiatives that would seal the records and make these reports unavailable to the plaintiff's bar. If the FDA truly wants to encourage accurate and complete reporting, this must not be at the expense of increasing physician and/or health care facility liability. Anything less would encourage under-reporting when facilities recognize a SUD malfunction or failure in the reprocessing that could be attributable to the reprocessed SUD.

An appropriate mechanism should be in place to enforce and review the FDA SUD classification

The AAOS believes that ensuring safe and effective devices in the marketplace is of paramount importance. However, we believe that the regulatory burden placed on the user and manufacturer community must be in proportion to the need to intervene because of the perceived and actual risk. The FDA has indicated that enforcement decisions will be made on a case-by-case basis. The AAOS encourages the FDA to solicit input on an ongoing basis from health care professionals who have significant expertise in the use of specified SUDs.

Moreover, the AAOS recommends implementing an appropriate appeals mechanism for device risk categorization and re-categorization. While the public has had the opportunity to comment on the risk assigned to SUDs listed in the guidance document dated February 8, 2000, we are concerned that the FDA has not proposed an appeals mechanism to dispute the risk categorization of devices labeled for single use which come to the market after the issuance of final guidance documents. For example, if a SUD comes to the market and is inadvertently categorized as a high risk device, we are concerned that this categorization and the regulatory requirements that would be placed on reprocessors and hospitals may affect the access to such a medical device.

Conclusion

In sum, we urge the FDA to present an understandable, predictable, and accountable process for stakeholders concerned with the regulation of SUDs, as well as a regulatory scheme that accurately reflects the actual risk and the need to ensure patient safety.

Again, we are pleased to have this opportunity to comment on this important issue, and we look forward to continuing to work with the FDA in determining the appropriate mechanism for the regulation of reprocessed single use devices. The AAOS appreciates the FDA's attempt to address reuse in an open and cooperative fashion and to seek the input and guidance of professional organizations.

Sincerely,

S. Terry Canale, MD

S. Terry Canale, M.D.
President

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